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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,195	10/31/2003	Linda M. Pacioretty	CLANACCR_001NP	4532

7590 09/28/2007

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EXAMINER	
CHONG, YONG SOO	
ART UNIT	PAPER NUMBER
1617	
MAIL DATE	DELIVERY MODE
09/28/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/699,195	PACIORETTY ET AL.	
	Examiner	Art Unit	
	Yong S. Chong	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) *1-20,25-27,30,31 and 36-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-24, 28-29, 32-35, 39-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

This Office Action is in response to applicant's arguments filed on 7/9/2007. Claim(s) 1-40 are pending. Claim(s) 21 and 32 have been amended. Claim(s) 1-20, 25-27, 30-31, 36-38 have been withdrawn. Claim(s) 21 (in part), 22-24, 28-29, 32 (in part), 33-35, 39-40 are examined herein.

Applicant's arguments have been fully considered but found not persuasive. The rejection(s) of the last Office Action are maintained for reasons of record and modified or repeated below for Applicant's convenience. The new claim amendments have necessitated the following new rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 32-35, 39-40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The limitation in claim 32 reciting "fasting hyperlipidemia" has no support in Applicant's disclosure.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham vs John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim(s) 21 (in part), 22-24, 28-29, 32 (in part), 33-35, 39-40 are rejected under 35 U.S.C. 103(a) as being obvious over McCleary (US Patent Application 2002/0132219 A1) in view of Applicant's admission of the prior art.

The instant claims are directed to a method for treating, preventing, or normalizing fat maldistribution or hyperlipidemia resulting from anti-retroviral treatment of HIV-1 infection in a subject by administering triglyceride of conjugated linoleic acid and a thiol-containing compound.

McCleary teach a nutritional supplement composition comprising conjugated linoleic acid and alpha-lipoic acid for modulating nutrient partitioning in a human (abstract). Disorders of nutrient partitioning include obesity (fat maldistribution) and

hyperlipidemia (section 0002). More particularly, it is desirable to provide a means for modulating aberrant pathways of nutrient partitioning so as to avoid excessive fat storage, to promote oxidation of fat, and reduce fat levels (sections 0006 to 0007). McCleary also discloses specifically triglyceride of conjugated linoleic acid (section 0010). McCleary also teach that fat synthesis and storage are diminished resulting in a fall in the intracellular fat content of the liver, pancreas, and skeletal muscle as well as a fall in visceral fat and total body fat stores accompanied by a decrease in individual fat cell volume (section 0023). Preferred amounts for CLA are 50 mg to 20 g and for alpha-lipoic acid are 25 mg to 2 g (Table 1).

Examiner notes that whether or not hyperlipidemia is caused by fasting or not, the etiology of the disorder is given little patentable weight since the excess fats and lipids in the blood will be reduced as a result of the same active agent being administered to the same patient population at the same dosage. Further, interpreting the term "fasting" in its broadest sense can be defined as simply skipping one meal or not eating overnight as stated in Applicant's remarks (first paragraph). By this definition, this would still read on the patient population disclosed in the cited prior art. Furthermore, it would have been obvious to one of ordinary skill in the art to have treated a species such as "fasting hyperlipidemia," when it is obvious to have treated the genus, "hyperlipidemia" as reflected in the cited prior art.

However, McCleary fail to disclose specifically a subject being treated with anti-retrovirals from an HIV-1 infection.

Applicant's disclosure of the prior art teaches that HIV infection is accompanied by disturbances in lipid and glucose metabolism. These metabolic abnormalities are further confounded by hypercholesterolemia, hypertriglyceridemia, and hyperlipidemia induced by anti-retroviral drugs. In fact, it is estimated that almost two-thirds of HIV/AIDS patients exhibit abnormal fat distribution coincident with AR-therapy (section 0003 to 0009).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to administer a nutritional supplement composition comprising conjugated linoleic acid and alpha-lipoic acid to treat a subject with fat maldistribution and hyperlipidemia resulting from anti-retroviral treatment of HIV-1 infection.

A person of ordinary skill in the art would have been motivated to administer a nutritional supplement composition comprising conjugated linoleic acid and alpha-lipoic acid to treat a subject with fat maldistribution and hyperlipidemia resulting from anti-retroviral treatment of HIV-1 infection because: (1) McCleary teaches the treatment of fat maldistribution and hyperlipidemia by administering a nutritional supplement composition comprising conjugated linoleic acid and alpha-lipoic acid, and (2) Applicant's admission of the prior art teaches that fat maldistribution and hyperlipidemia are common in HIV/AIDS patients who are receiving anti-retroviral treatment. Therefore, one of ordinary skill in the art would have had a reasonable expectation of success in treating not only patients suffering from fat maldistribution and

hyperlipidemia, but also from patients suffering from fat maldistribution and hyperlipidemia resulting from anti-retroviral treatment of a HIV-1 infection.

Response to Arguments

Applicant argues that McCleary fails to disclose any viral disease, such as HIV or AIDS, as a disorder of nutrient partitioning. This is not persuasive because although the etiologies may be different, it is clear as cited in the prior art that both fat maldistribution and hyperlipidemia are common to HIV and AIDS patients.

In response to applicant's arguments against the references, one cannot show nonobviousness by attacking references individually where the rejections are based on the combination of references. See *In re Keller*, 642 F. 2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F. 2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicant argues that the method of McCleary suppresses appetite, a condition unwanted in persons with HIV infection. This is not persuasive because while this may be true, it does not change or take away from the fact that cited prior art teaches a method for treating, preventing, or normalizing fat maldistribution or hyperlipidemia resulting from anti-retroviral treatment of HIV-1 infection in a subject.

Applicant argues that McCleary describes a formulation for the reduction of total body fat, whereas the claims of the instant application reflect a formulation that results in a targeted redistribution of body fat, specifically a loss of visceral fat while maintaining or increasing subcutaneous fat.

This is not persuasive because at the outset, the limitations addressed above are not found in the claims. Moreover, when the same active agent is administered to the same patient population at the same dosage, the mechanism of action is inherent.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

"Products of identical chemical composition can not have mutual exclusive properties." Any properties exhibited by or benefits from are not given any patentable weight over the prior art provided the composition is inherent. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure; the disclosed properties are necessarily present. *In re Spada*, 911 F.2d 705,.709, 15 USPQ 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01. The burden is shifted to the applicant to show that the prior art product does not inherently possess the same properties as the instantly claimed product.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

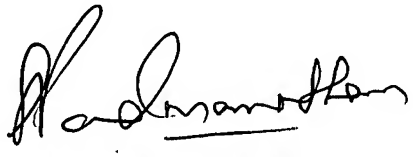
TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

YSC



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER